



Spain implements control mechanisms in order to avoid excessive parallel trade

Circular 2/2012 of the Spanish Medicines Agency regarding the “Prior notification of shipments of medicinal products to other Member States”

Background

Over the last years we have witnessed a gradual increase of supply shortages of certain medicinal products. Even though such episodes are limited and take place occasionally, they have been cause for concern. These episodes have always been followed by the well-known exchange of mutual accusations between the pharmaceutical industry and the distribution sector. The pharma industry repeatedly reproaches the distributors for their pursuit of profit by reselling units to other Member States that should have been aimed at supplying our local pharmacies. For their part, the distributors have counterattacked by accusing the manufacturers of the medicinal products of limiting the supply of some of their medicines, in order to prevent that such business practice ends up hurting the sales of their products in other countries.

It is never fair to generalise but is beyond doubt that the pharmaceutical companies are supplying our market with a larger number of units every year. And it is only logical that nothing more can be asked of them. It is the pharmaceutical industry's obligation to cover the specific needs of our territory, and it is neither fair, reasonable nor realistic to expect the industry to dedicate its efforts to supplying the distribution sector without any limits, with the sole purpose of enabling the distributors to continue to make profit with parallel trade indefinitely.

The Government says no to the right to be supplied and to excessive parallel trade

The Government seems to have come to the same conclusion, because finally it has eliminated such alleged generic right of the wholesalers to be supplied without limits by the pharmaceutical industry from the draft Royal Decree on distribution.

Moreover, the Spanish Agency for Medicinal Products and Medical Devices (AEMPS for its abbreviation in Spanish) has also decided to take action in this field with its new Circular 2/2012, with which it implements a new control mechanism as regards the shipments of medicinal products to other Member States. As of July wholesalers must notify their shipments to other Member States of those medicines the shortage of which could have an impact on health assistance. The list of products affected by this measure, which is available on the website of the AEMPS, shall be updated periodically in accordance with suggestions made by the Autonomous Regions, associations and healthcare professionals. The notification must be sent telematically, at least three business days prior to the shipment, and the AEMPS reserves the right to veto the operation in the event that the product to be shipped has presented supply shortages. The AEMPS shall inform the Autonomous Regions so that they may adopt the appropriate control measures and the AEMPS may also request information from the marketing authorisation holder of the product whenever it considers this to be necessary.